REMARKS

The Official Action dated April 9, 2002 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 has been amended for a matter of clarity only, care having been exercised to avoid any introduction of new matter. A Version With Markings Showing Changes Made is attached. It is believed that this amendment does not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Applicants acknowledge with appreciation the Examiner's indication that claims 4, 5, 10-13 and 15-20 are allowed.

Claims 1-3, 6-9 and 14 were rejected under 35 U.S.C. § 112, first paragraph. on the basis that the specification does not reasonably provide enablement for the use of any ABPA-related allergen. The Examiner asserts that the claims are drawn to the use of any ABPA-related allergen to discriminate with 100% specificity the difference between ABPA and allergic sensitization to *A. fumigatus*. The Examiner relied on Little et al, *Journal of Allergy and Clinical Immunology*, 198(1): 55-63 (July 1996) as teaching the state of the art wherein an ABPA allergen discriminated between ABPA and allergic sensitization to *A. fumigatus* with only 78.5% specificity. The Examiner also asserted that the state of the art recognizes that it is unpredictable whether or not a given ABPA allergen can discriminate with 100% specificity, whereby it would require an undue amount of experimentation to practice the full scope of the claim invention.

However, Applicants submit that the methods defined by claims 1-3, 6-9 and 14 are fully enabled by the present specification in accordance with the requirements of 35 U.S.C. §

112, first paragraph. Accordingly, the rejection is traversed, and reconsideration is respectfully requested.

More particularly, claim 1 is directed to methods for the diagnosis of ABPA in a human individual. The methods comprise determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens which discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*. Claims 2, 3, 6-9 and 14 directly or indirectly depend from claim 1.

Contrary to the Examiner's assertion that Applicants' claims are drawn to use of any ABPA-related allergens to discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*, Applicants submit that claim 1 is directed to methods which employ only ABPA-related allergens which discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*. Thus, the present methods do not employ allergens as described by Little et al which exhibit only 78.5% specificity. While the present inventors do not intend to be bound by theory, the purified protein 66 of Little et al is of a higher molecular weight (66 kDa), where the proteins exemplified in the present specification are of a lower molecular weight (40 and 28 kDa as set forth in Table 2 at page 22 of the specification).

Additionally, contrary to the Examiner's assertion that it is unpredictable whether or not a given ABPA allergen can discriminate with 100% specificity the difference between ABPA and allergic sensitization to *A. fumigatus*, whereby it would require an undue amount of experimentation to practice the claimed invention, the present specification demonstrates that it is well within the ability of one of ordinary skill in the art to determine if an ABPA-related recombinant allergen discriminates with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*. In fact, the examples of the present specification demonstrate the specificity determination can be easily made. In this regard, the Examiner's attention is

directed to the techniques and procedures set forth in the specification at pages 12-16. Thus, it is within the ability of one of ordinary skill in the art to determine if an ABPA-related recominant allergen discriminates with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*, in accordance with the techniques disclosed in the present application, whereby the diagnosis methods defined by claim 1 are fully enabled by the teachings of the present specification.

It is well settled that enablement is not precluded by the necessity for some experimentation such as routine screening, and a considerable amount of experimentation is permissible if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed, *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). In the present application, as in the *Wands* application, the specification provides guidance as to any experimentation which is required and provides working examples. Thus, the present specification, as in *Wands*, is enabling for the claimed methods.

It is therefore submitted that the present specification enables the methods of claims 1-3, 6-9 and 14, whereby the rejection under 35 U.S.C. § 112, first paragraph, has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. § 112, first paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES MADE

Claim 1 is amended as follows:

1. (Fourth Amendment) A method for the diagnosis of ABPA in a human individual, comprising determining if the individual carries antibodies reactive with one or more ABPA-related recombinant allergens[,] which [one or more ABPA-related recombinant allergens] discriminate with 100% specificity between ABPA and allergic sensitization to *A. fumigatus*.